Application No.: 09/787,079 Inventor: ROSENBERG et al.

Docket No.: 0480/01216

REMARKS/ARGUMENTS

Amendments to the Claims

Applicant has amended independent claims 1, 12 and 13. Support for the amendments to

claims 1 and 13 can be found at least at page 4, lines 6 - 27 of the original specification and

FIGS. 1-3. Support for the amendments to claim 12 can be found at least at page 3, lines 4 – 14

of the original disclosure and FIGS. 1-3.

Claim Rejections under 35 USC § 102

Claims 13 and 15-17 stand rejected as allegedly anticipated by Dabal et al. Applicant has

amended independent claim 13 to recite that singulating is provided by "asserting a force having

a component perpendicular to the plane of the tablet belt to said tablet belt, said force generated

by diverting the solidified tablet belt out of its transport plane," which features are not described

by Dabal et al.

Additionally, it should be further appreciated that Dabal et al. fails to describe an

extruded pharmaceutical mixture that is formed into product tablets as described by claim 13.

That is, Col. 15, line 30 – Col. 19, line 5 of Dabal et al. specifically describe a laminate dosage

form wherein an active ingredient is deposited on a surface of a moving web. Such deposition

and methodology, "constitutes [a] radical departure from methods of incorporating active

ingredients into conventional dosage forms."

Furthermore, contrary to the Examiner's assertion, Dabal et al. also fails to describe a

tablet web including product webs. More specifically, the Examiner asserts that elements 82 and

85 of FIG. 5 of Dabal et al. describe individual tablets as being connected by product webs.

However, Column 22, lines 4 - 19 of Dabal et al., which further describes FIG. 5, specifically

sets forth that "the output of the rotary dosage forming station is a continuous chain of end-

connected dosage units." (Emphasis added). Such end to end configuration is more

appropriately illustrated in FIG. 5 itself, which specifically shows each dosage unit as being

connected to one another, end to end, with there being no intermediate product web

connected to one another, that to that, with there being no intermediate product week

therebetween. Accordingly, Dabal et al. specifically illustrates and specifically describes end-

connected dosage units and does not describe intermediate product webs.

Finally, with regard to the Examiner's assertion that "[i]t is noted that ambient cooling

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will take place along the transport sections," such assertion is wholly unsupported by the record. In fact, the Klimesch et al., which is cited by the Examiner in the rejection of Applicant's claims under 35 USC \S 103, specifically sets forth that melts have varying cooling rates and the invention described therein provides solutions related to "the processing of only slowly hardening melts." (Col. 1, lines 23 - 26). Accordingly, the Examiner's assertion that ambient cooling will take place to sufficiently solidify the tablet web for singulation is completely unsupported.

In view of the above, inasmuch as they may apply to the claims as amended, the rejection of claim 13 and those claims depending therefrom should be withdrawn.

Claim Rejections under 35 USC §103

Claims 1-5, 7-9, 11, 12 and 14 stand rejected as being obvious in view of Dabal et al. in view of Klimesch et al.

With regard to independent claim 1, Applicant has amended claim 1 to recite that during singulation, "a force having a component perpendicular to the plane of the tablet belt is asserted upon the tablet belt, the force being generated by diverting the solidified tablet belt out of its transport plane," which features are not described by either of Dabal et al. nor Klimesch. More specifically, contrary to the Examiner's assertion, neither of Dabal et al. nor Klimesch describe tablet belts comprising product webs disposed therebetween. As previously indicated, Column 22, lines 4 – 19 and FIG. 5 of Dabal et al, specifically sets forth that "the output of the rotary dosage forming station is a continuous chain of end-connected dosage units." (Emphasis added). Similarly, Klimesch does not describe a product webs disposed between tablets. Accordingly, neither describe a force generated by diverting the solidified tablet belt out of its transport plane. Additionally, it should be further appreciated that while Klimesch, arguably, describes a continuous process on the whole, it does not describe a continuous product strip. In this regard, none of the figures or the specification illustrates or describes the extrusion of a continuous product strip. Withdrawal of the rejection, insamuch as it may apply to the claims as amended, is requested.

With regard to independent claim 12, Applicant has amended such claim to recite that the "extruder means form[s] a tablet belt comprising individual tablets connected by a product web," which features are not described by either of Dabal et al or Klimesch. As previously indicated,

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Column 22, lines 4 - 19 and FIG. 5 of Dabal et al, specifically sets forth that "the output of the

rotary dosage forming station is a continuous chain of end-connected dosage units," (Emphasis

added) such that there exist no product webs. Similarly, Klimesch does not describe product

webs disposed between tablets. In this regard, none of the figures of Klimesch illustrate product

webs and none of Klimesch describes or illustrates means for singulating tablets from a cooled

tablet belt comprising tablets and product webs, application of a force thereupon or diverting of

the solidified tablet out of the transport plane (See FIG. 1 which illustrates transport plane 34).

In view thereof, Applicant respectfully requests that the rejections be withdrawn.

Conclusion

Applicants respectfully submit that the present application is in condition for allowance,

which action is courteously requested. Please charge any shortage in fees due in connection with

the filing of this paper to Deposit Account 14.1437. Please credit any excess fees to such

account.

Respectfully submitted,

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